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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/535,000

05/16/2005

Masakazu Hatano

05318/HG

1933

1933 7590 05/28/2009

FRISHAUF, HOLTZ, GOODMAN & CHICK, PC
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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/535,000	Applicant(s) HATANO ET AL.	
	Examiner GIGI HUANG	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-12 is/are pending in the application.
- 4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/16/2005, 6/27/2005, 8/16/2007, 4/21/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application

1. The response filed February 24, 2009 has been received, entered and carefully considered. The response affects the instant application accordingly:
 - a. Claims 1-2, 6 have been amended.
 - b. Claim 3 has been cancelled.
2. Claims 1-2, 4-12 are pending in the case.
3. Claims 1-2 and 4 are present for examination.
4. The text of those sections of title 35.U.S. Code not included in this action can be found in the prior Office action.
5. All grounds not addressed in the action are withdrawn or moot.

Priority

6. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of the translation of the foreign priority papers submitted under 35 U.S.C. 119(a)-(d), the claim is perfected.

Information Disclosure Statement

7. The IDS filed 5/16/2005, 6/27/2005, 8/16/2007, 4/21/2008 have been considered except for JP-2726672 which is not on the search report and has no translation (filed 6/27/2005) and are enclosed in the action. The request for WO 00/09162 as being not presently of record is inaccurate as it is of record on the IDS filed 8/16/2007 seventh entry under Foreign Patent Documents and is present in the prior art submitted.

Response to Arguments

8. Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azuma et al. (WO 00/09162).

Claim 3 is cancelled, the rejection is moot.

Applicant's arguments filed 2/24/2009 have been fully considered but they are not persuasive. Applicant asserts that Azuma does not teach or suggest a combination of a Rho kinase inhibitor or the combination of a Rho kinase inhibitor with a beta-blocker. Applicant asserts that that combinations of drugs to have an additive effect can be limited and cites that while some combinations for glaucoma have an additive effect, some do not, citing beta-blocker/alpha-2-agonists, beta-blockers/sympathomimetics, pilocarpine/anticholinesterase, and asserts that one of skill in the art would not necessarily expect desired results from combining agents. This is not accurate as the translation states that the combination of beta-blockers/alpha2 agonists cannot be expected to have an additive effect but it does not say that it does not have an additive effect and in fact, the combination is patented and the additive combination is known in the art (e.g. apaclonidine and timolol, see Konstas et al. and DeSantis). Not every combination of drugs must be additive, but as addressed by the art and Applicant's references, combination therapy is well known in the art and it is obvious to one of skill in the art to combine two drugs known for the same purpose to form a combined composition for that purpose with a reasonable expectation of therapeutic efficacy. The arguments are also not persuasive as Azuma does teach that the Rho kinase inhibitor compound can be used alone or in combination with several kinds of compounds (Col. 9

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line 3-5, i.e. teaches combination therapy). As addressed by both Fukuchi (the partial translation provided by Applicant) and DeSantis (USP 5502052 previously cited), it is well known in the art that combination therapy with beta-blockers can have additive effects with several glaucoma drugs such as parasympathetic agonists, carbonic anhydrase inhibitors, prostaglandins, alpha one-blockers (Fukuchi); and that it is known that two or more different types of drugs are sometimes required to achieve therapeutic control of the intraocular pressure (DeSantis Col. 2 line 34-48). Azuma also teaches combinations of compounds for the same use. It would be obvious to one of skill in the art to combine known glaucoma agents for the same purpose with a reasonable expectation of success with routine experimentation and one would be motivated to do so to attain therapeutic control at the desired levels. In regards to the assertion of unpredictable results, the figure shows an additive result in the combination of the Y-39983 and the timolol. The additive result is not unexpected and would be expected to be more than the individual drugs alone.

Accordingly, the rejection is maintained.

Conclusion

9. Claims 1-2 and 4 are rejected.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Zohreh A Fay/

Primary Examiner, Art Unit 1612